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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/091,744      | 03/05/2002  | Andrew Holman        | 020862-000110US     | 8465             |

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EXAMINER

CRIARES, THEODORE J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/091,744

Applicant(s)

HOLMAN, ANDREW

Examiner

Theodore J. Criares

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 and 40-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-29 and 40-45 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**CLAIMS 1-29 AND 40-45 ARE PRESENTED FOR**  
**EXAMINATION**

**DETAILED ACTION**

Applicant's election with traverse of the method of treating rheumatoid arthritis by administering a therapeutic agent and an effective amount of a sleep restorative agent, wherein the therapeutic agent is prednisone and that sleep restorative agent is pramipexole, whereby the therapeutic agent is decreased, as compared to a subject not receiving the sleep restorative agent, in Paper dated January 13, 2004 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the examiner in the examination of the subject application. This is not found persuasive because searches in different classifications is required since the agents which treat arthritis are different than agent that would be required to treat Myasthenia gravis since each medical disorder has a different etiology. The active agents required to treat one disorder would not be required to treat the other disorder. Therefore, an undue burden is placed on the examiner since various compounds have to be searched which would be classified throughout class 514, e.g., brequinar and leflunomide. Brequinar is classified in Class 514, subclass 312 and leflunomide is classified in class 514, subclass 378. An undue burden would be placed on the examiner in view of the required literature search for the various diseases claimed.

This requirement is still deemed proper and is therefore made FINAL.

### ***Election/Restrictions***

A careful review of applicant's claims and elections necessitates the following restriction under 35 U.S.C. 121.

Inventions to compounds which are 1) active as sleep restorative agents per se and 2) sleep restorative agents which are capable of reducing the amount of a therapeutic agent required to treat arthritis are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention of the use of pramipexole has separate utility such as it is used in the treatment of Parkinson's disease. See MPEP § 806.05(d).

The two separate inventions are distinct since the sleep restorative agent have a separate known activity, activity in the treatment of Parkinson's disease than that presently claimed, i.e., a sleep restorative agent. In addition to the activity claimed it also has the activity of reducing the amount of therapeutic agent required in the treatment of arthritis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.


The examiner acknowledges the errors in the previous numbering of the groups and has corrected the numbering to reflect them to be from I to XXXIX

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Criares whose telephone number is (571) 272-0625. The examiner can normally be reached on 6:30 A.M. to 5:00P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Theodore J. Criares  
Primary Examiner  
Art Unit 1617

4/26/04  
tjc